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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/743,394

Applicant(s)

DORKEN ET AL.

Examiner

Lisa Gansheroff

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) 1-7 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *detailed action*

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DETAILED ACTION

Pending claims: 1-7.

Response to: Preliminary Amendment filed 07 February 2001.

Specification

It is not clear whether the title of the invention is intended to be the title on the Oath/Declaration or the title as written on the first page of the specification.

Claim Objections

Claims 1-7 are objected to because of the following informalities: Claim 1 recited "the production of Ad vector", and it appears that a word such as "an" is missing between "of" and "Ad" in line 1 and between "for" and "Ad" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method for the optimization of the production of Ad vector, but the recited steps only comprise transferring the gene or cDNA for p21 into a cell line. Since there is no step in which any Ad vector is produced, the claim lacks a nexus between the preamble and the result of the method steps.

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Claims 2-5 recite utilizing a promoter, but it is not clear how this promoter is related to the p21 gene/cDNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Since the word "gene" refers not only to a coding sequence but also to an entire genomic structure (including introns and all regulatory regions upstream and downstream of coding sequences), and since it is not clear that the entire genomic sequence of the p21 gene is known, these claims are subject to a rejection for an inadequate written description based on the use of the word "gene". It is suggested that the word gene be replaced with terminology such as "nucleic acid sequence".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The claims are drawn to methods comprising steps of transferring the gene or cDNA of p21 into a cell line. The recitation of the indented use of the method for production of Ad vector has not been given patentable weight because the recitation occurs in the preamble; there are no method steps in which Ad vector is produced. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Vogt et al. (February, 1998. Cell Growth and Differentiation 9:139-146).

Vogt et al. teaches transferring the cDNA of p21 into cells using the pCLXN vector. See page 142, right column and Fig. 5. In order to provide background information about the pCLXSN vector, the Naviaux et al. reference which was cited by Vogt et al. (as reference 22 of Vogt et al.) is mentioned here. It is emphasized that the Naviaux et al. reference is not part of the 102(b) rejection, since Vogt et al. teaches everything necessary to anticipate the instant claims. The Naviaux et al. reference is included merely to show that the vector used by Vogt et al. is a retroviral vector. Naviaux et al. note that the pCL vectors are retroviral vectors (see Abstract).

Since retroviral vectors integrate into the genome, cells into which these vectors are introduced would be stably (not transiently) transfected, based on the definitions of stable (as integration into the chromosome) and transient (as remaining epichromosomal) in the instant specification, page 3. Additionally, since different cell lines can be infected by retroviral vectors, the method is independent of the cell line used. Since Adenovirus can infect different cell lines, absent evidence to the contrary, the cells of Vogt et al. can be used as a production cell line for Ad vector. Further, as Vogt et al. do not describe regulating the promoter for p21, absent evidence to the contrary the promoter is constitutive, as p21 appears to be expressed upon transfection (see Fig. 5).

Claims 1, 3, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nobuyuki et al. (Feb 1998. Oncogene 16:705-712).

Nobuyuki et al. teach transferring the cDNA for p21 with a regulatable promoter (the LacSwitch promoter which is regulatable with IPTG) into cell lines. The cells are stably transfected. page 710, right column, and Abstract). Absent evidence to the contrary, the cells of Nobuyuki et al. can be used as a production cell line for Ad vector.

Claims 1, 3, 4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Niculescu et al. (Jan. 1998. Molecular and Cellular Biology 18:629-643).

Niculescu et al. teach transferring the cDNA for p21 into cell lines. One method comprises utilizing a promoter that is regulatable by tetracycline, and the cell line is stable transfected. A second method comprises utilizing a constitutive promoter (CMV) and an Ad

(adenoviral) vector. Since adenoviruses do not integrate into the genome, in this second method the cells are transiently transfected. See page 630, Materials and Methods section. The vector used to transfer p21 is an Ad vector.

Claims 1, 4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al. (1994. Experimental Cell Research 211:90-98).

Noda et al. teach transferring the cDNA for p21, which is referred to as "sdi1", into cells using a constitutive promoter, the SR α promoter, and the cells are transiently transfected. See the first paragraph of Results on pages 91-92, and the Abstract.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nabel et al. (U.S. Patent 5,863,904).

Nabel et al. teach transferring the cDNA for p21 into cell lines. Nabel et al. teach that expression vectors for p21 can be eukaryotic and viral vectors, including retroviral or adenoviral vectors, and that the expression vectors can additionally contain regulatory elements. See column 2, lines 54-67 to column 3 lines 1-36. Also, see column 9, lines 54-57, in which an Ad vector is produced by transferring the p21 cDNA into a production cell line for Ad vector; the p21 is carried by the Ad vector. Also, see column 10 lines 1-27. Thus, Nabel et al. suggests both stable and transient transfection, and, absent evidence to the contrary, the teachings of Nabel et al. encompass both constitutive and regulatable promoters.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Gansheroff whose telephone number is (703) 605-1203. The examiner can normally be reached 9 AM - 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Dianiece Jacobs whose telephone number is (703) 305-3388 or to the receptionist whose telephone number is (703) 308-0196.

LG
April 19, 2001



JAMES KETTER
PRIMARY EXAMINER